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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,839	09/16/2003	Tim Clarot	33205.1900	4908

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EXAMINER	
ALSTRUM ACEVEDO, JAMES HENRY	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 12/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/664,839	CLAROT ET AL.	
	Examiner	Art Unit	
	James H. Alstrum-Acevedo	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-35* is/are rejected.

7)☒ Claim(s) *21 and 27* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/27/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-35 are pending.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim 22 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 22 recites the limitation, "further comprising an active substance" and depends from independent claim 21, which already comprises an active substance. Therefore, claim 22 does not further limit claim 21.

Claim 27 is objected to because of the following informalities: a space should be inserted between numbers and the units associated between said numbers. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 2-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is confusing because it utilizes the term "allergy-relief substances" as well as anti-histamines, which are used to treat allergies. It is unclear what is the difference between "allergy-relief substances" and anti-histamines.

The term "allergy-relief substances" is not defined in the specification. It is unclear if the Applicant intends this term to solely encompass anti-histamines or whether it includes other substances. If the Applicant's intention is the latter, it is unclear what the other substances may be. Clarification is requested.

Claims 2 and 34 require the limitation that the composition includes an active substance. The term active substance is not defined in the specification, rather examples are given: decongestants, moisturizers, homeopathic compounds, and naturopathic materials. An ample list of decongestants is provided, however, it is unclear what Applicant considers homeopathic compounds and naturopathic materials. The intended scope of the term "pharmaceutical substances" is also unclear. For this reason, a person of ordinary skill in the art would be unable to ascertain the intended scope of the term "active substance."

Claims 3 and 23 are indefinite because they use one or more of the following undefined terms: homeopathic substance, mineral, naturpathic material, and pharmaceutical substance.

Claim 21 recites a composition limitation reading "a viscosity sufficient to maintain the composition in contact with a nasal membrane for an extended period of time." It is not apparent what is considered a "sufficient viscosity" or what amount of time constitutes an "extended period of time." Clarification is requested.

Claim 12-14, 26, and 27 are confusing because these claims recite the limitation "...the active substance is zinc in a zinc composition..." It is unclear what meaning the Applicant intends to convey by the phrase zinc in a zinc composition. This is especially confusing in claims 12 and 26, wherein the claims recite, "...zinc in a zinc composition further comprising a zinc gluconate concentration in a range of about..." This phraseology creates uncertainty as to

whether the concentration amounts listed are in reference to zinc or to zinc gluconate or the zinc composition in the base composition. Similar uncertainty regarding what the concentration amounts refer to is found in claims 13-14 and 27.

The remaining claims are rejected as being dependent upon a rejected claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7, 12-18, 21-30, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seifert (U.S. Patent No. 5,100,028) in view of Davidson (U.S. Patent No. 6,365,624).

Seifert teaches a **rupturable flexible fluid dispenser** including a flexible fluid-containing vessel, which has a seal, which **seals a top wall of the vessel to a bottom wall** and is shaped to concentrate in a region thereof forces resulting from pressure generated **by applying a force to the dispenser.** The dispenser contains an applicator similar in design and shape to that claimed in the instant application (title, abstract, Figures 1-3).

Seifert teaches that the applicator may be used to apply a **sterile dosage of cream to the body or to apply a chemical to a particular surface** (column 5, lines 2-4). The word chemical is understood to encompass the term active substance.

Seifert lacks the teaching of a specific composition, including compositions having a viscosity greater than 1,500 centipoises and compositions having specific thickeners (e.g. carrageenan), a carrier comprising glycerin, and further comprising menthol, which are applied to the nasal membrane.

Davidson teaches a composition for reducing the duration of a common cold comprising: about **90 to about 99.1 weight percent of a carrier**; **about 0.9 to about 2.0 weight percent zinc gluconate**, wherein said composition has a **viscosity greater than about 5,000 centipoise**, wherein the carrier includes **glycerin** in an amount of about **0.05 to about 3.0 weight percent,** further comprising a thickener selected from the group consisting of: **carbohydrate thickeners,**

carrageenan, sugar, guar gum, and methylcellulose, and further comprising about **0.01 to about 0.10 weight percent methanol** (claims 9-14).

Davidson teaches that the composition has a viscosity in the range of 5,000 to 20,000 centipoise (column 2, lines 18-19).

Davidson also teaches **a method of applying a zinc gel composition to a nasal membrane** (claims 1-8).

Davidson teaches that ionic zinc is a known effective anti-rhinovirus agent in vitro and in vivo (column 1, lines 21-22).

Davidson teaches that **menthol** is a **decongestant** and a bronchial dilator (column 6, lines 1-8).

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the composition resulting from the teachings of Davidson with the applicator assembly taught by Seifert, because Seifert teaches that his applicator may be used to apply a sterile dosage of cream to any part of the body and chemicals to a surface. It would have been apparent to a skilled artisan that the term "chemical" encompasses active substances (pharmaceuticals, homeopathic compounds, etc) and that it is desirable for a composition used in medical, pharmaceutical, and/or homeopathic applications to remain sterile. The viscosity of the composition as stated in claims 1 and 35 set the minimal viscosity at about 1,500 centipoise and claim 35 limits the maximum viscosity to about 40,000 centipoise. The viscosity range contained within the instant application overlaps that taught by Davidson and is therefore obvious, because viscosity is a physical characteristic of the composition that may be modified via the amount of thickeners used in the composition. The modification of a composition's

physical characteristics (e.g. viscosity) to obtain an optimized composition was within the ability of a person of ordinary skill in the art at the time of the instant application. In the instant application, optimization of viscosity would have been achieved through the adjustment of the quantities and types of thickeners present in the composition. Regarding the method of claim 35, the steps of said method would have been obvious to a person of ordinary skill in the art aware of the teachings of Seifert and Davidson to provide an applicator having an elongated stick, wherein the applicator contains a composition (Seifert) and is contained within a container, applying force to sever the container into two portions (Seifert), exposing the applicator, and applying the composition to a nasal membrane (Davidson). Regarding the amounts of components stated in the instant application, the amount of a specific, ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention.

Claims 8-11, 19-20, and 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seifert in view of Davidson (U.S. Patent No. 6,365,624) as applied to claims 1-7, 12-18, 21-30, and 35 above, and further in view of Haslwanter et al. U.S. Patent No. 5,854,269).

The teachings of Seifert and Davidson have been set forth above.

Seifert and Davidson lack the teaching of permeation enhancers (e.g. disodium EDTA), preservatives (e.g. benzalkonium chloride), and pharmaceutically acceptable buffers, including phosphate buffer.

Haslwanter teaches that an over-the-counter (OTC) product under the trade name AFRIN® comprises a composition containing vapors of **menthol**, **eucalyptol** and **camphor, oxymetazoline hydrochloride,** and an aqueous carrier containing **benzalkonium chloride**, **glycerine**, phenylmercuric acetate, sorbitol, polysorbate 80 is currently available (column 1, lines 37-44).

Haslwanter teaches in nasal compositions comprising **oxymetazoline or a pharmaceutically acceptable salt thereof**, **benzyl alcohol (a preservative)**, a surfactant (i.e. emulsifier), **disodium EDTA**, **benzalkonium chloride**, and pharmaceutically acceptable **buffers**, including **phosphate**. In Example 2, Haslwanter teaches several specific surfactants, including a **fatty acid ester of polyethylene glycol, and specific buffers (sodium phosphate monobasic and sodium phosphate dibasic)** (i.e. Polysorbate 80) (column 2, lines 40-45, 56-60, 65-67; column 3, lines 1, 13-15, 23-27, 28-33; and Example 2). Examples 3-5 teach similar compositions.

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the composition resulting from the teachings of Davidson and Haslwanter with the applicator assembly taught by Seifert, because Seifert teaches that his applicator may be used to apply a sterile dosage of cream to any part of the body and chemicals to a surface. It would have been apparent to a skilled artisan that the term "chemical" encompasses active substances (pharmaceuticals, homeopathic compounds, etc) and that it is

desirable for a composition used in medical, pharmaceutical, and/or homeopathic applications to remain sterile. Regarding the composition, it is obvious to combine known decongestants, per the teaching of Davidson, and furthermore a commercially available OTC decongestant at the time of the instant invention was known to comprise a mixture of decongestants, water, an emulsifier, and a preservative. Haslwanter does not teach disodium EDTA as a permeation enhancer, nonetheless this is a property of disodium EDTA, and a compound cannot be separated from its properties. As a result, Haslwanter's compositions obviously contained a permeation enhancer. A skilled artisan would have had a reasonable expectation of success upon combining the teachings of Davidson and Haslwanter, because both teach aqueous decongestant compositions comprising menthol and glycerine had been used in the art at the time of the instant invention in an OTC decongestant containing components similar to the teachings of Haslwanter. Regarding the amounts of components stated in the instant application, the amount of a specific, ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention.

Claims 1-7, 12-18, 21-30, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Korteweg (EP 0357261) in view of Davidson (U.S. Patent No. 6,365,624).

Korteweg teaches a dry handle swab assembly and unit, wherein a substance to be applied is contained within the same sleeve as the swab (i.e. an applicator), and wherein the sleeve may be opened by use of manual force (abstract and Figure 4).

Korteweg teaches that the sleeve is manually compressible and severable in thin sections and it has a **handle portion** at one end, a **receptacle portion** at the other end, and a **transition portion** there between (column 2, lines 10-16).

Korteweg teaches that the swab assembly will be employed for the application of liquids or powders to the body (e.g. for medicinal, disinfectant, cosmetic, and cleansing purposes) (column 6, lines 16-20)

Korteweg lacks the teaching of a specific composition, including a viscous composition, and a method of delivering a composition to the nasal membrane.

The teachings of Davidson (USPN '624) have been set forth above.

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the composition of Davidson with the applicator assembly taught by Korteweg, because Korteweg teaches that the swab assembly will be employed for the application of liquids or powders to the body (e.g. for medicinal, disinfectant, cosmetic, and cleansing purposes). Regarding the composition, it is obvious to combine known decongestants, per the teaching of Davidson, and furthermore a commercially available OTC decongestant at the time of the instant invention was known to comprise a mixture of decongestants, water, an emulsifier, and a preservative. The viscosity of the composition as stated in claims 1 and 35 set the minimal viscosity at about 1,500 centipoise and claim 35 limits the maximum viscosity to about 40,000 centipoise. The viscosity range contained within the instant application overlaps

that taught by Davidson and is therefore obvious, because viscosity is a physical characteristic of the composition that may be modified via the amount of thickeners used in the composition. The modification of a composition's physical characteristics (e.g. viscosity) to obtain an optimized composition was within the ability of a person of ordinary skill in the art at the time of the instant application. In the instant application, optimization of viscosity would have been achieved through the adjustment of the quantities and types of thickeners present in the composition. Regarding the method of claim 35, the steps of said method would have been obvious to a person of ordinary skill in the art aware of the teachings of Korteweg, and Davidson to provide an applicator having an elongated stick, wherein the applicator contains a composition (Korteweg) and is contained within a container, applying force to open the container (Korteweg), exposing the applicator, and applying the composition to a nasal membrane (Davidson). The combined teachings of Korteweg and Davidson would have provided the skilled artisan with a reasonable expectation of success, because Davidson teaches all the components and Korteweg teaches an applicator containing a medicinal, disinfectant, cosmetic, or cleansing composition. Regarding the amounts of components stated in the instant application, the amount of a specific, ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention.

Claims 8-11, 19-20, and 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Korteweg (EP 0357261 in view of Davidson (U.S. Patent No. 6,365,624) as applied to claims 1-7, 12-18, 21-30, and 35 above, and further in view of Haslwanter et al. (U.S. Patent No. 5,854,269).

The teachings of Korteweg and Davidson have been set forth above.

Korteweg and Davidson lack the teaching of permeation enhancers (e.g. disodium EDTA), preservatives (e.g. benzalkonium chloride), and pharmaceutically acceptable buffers, including phosphate buffer.

The teachings of Haslwanter (USPN '269) have been set forth above.

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the composition resulting from the teachings of Davidson and Haslwanter with the applicator assembly taught by Korteweg, because Korteweg teaches that the swab assembly will be employed for the application of liquids or powders to the body (e.g. for medicinal, disinfectant, cosmetic, and cleansing purposes). Regarding the composition, it is obvious to combine known decongestants, per the teaching of Davidson, and furthermore a commercially available OTC decongestant at the time of the instant invention was known to comprise a mixture of decongestants, water, an emulsifier, and a preservative. Haslwanter does not teach disodium EDTA as a permeation enhancer, nonetheless this is a property of disodium EDTA, and a compound cannot be separated from its properties. As a result, Haslwanter's compositions obviously contained a permeation enhancer. A skilled artisan would have had a reasonable expectation of success upon combining the teachings of Davidson and Haslwanter, because both teach aqueous decongestant compositions comprising menthol and glycerine had

been used in the art at the time of the instant invention in an OTC decongestant containing components similar to the teachings of Haslwanter. Regarding the amounts of components stated in the instant application, the amount of a specific, ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 29 of copending Application No.

10/663,010 (copending '010) in view of Seifert (U.S. P.N. 5,100,028; USPN '028). Although the conflicting claims are not identical, they are not patentably distinct from each other because these claims are overlapping in scope.

Seifert teaches a **rupturable flexible fluid dispenser** includes a flexible fluid-containing vessel, which has a seal, which **seals a top wall of the vessel to a bottom wall** and is shaped to concentrate in a region thereof forces resulting from pressure generated **by applying a force to the dispenser.** The dispenser contains an applicator similar in design and shape to that claimed in the instant application (title, abstract, Figures 1-3).

Seifert teaches that the applicator may be used to apply a **sterile dosage of cream to the body or to apply a chemical to a particular surface** (column 5, lines 2-4). The word chemical is understood to encompass the term active substance.

It would have been obvious to a person of ordinary skill at the time of the instant application to combine the teachings of Seifert and copending '010, because Seifert teaches that his applicator may be used to apply a sterile dosage of cream to any part of the body and chemicals to a surface. It would have been apparent to a skilled artisan that the term "chemical" encompasses active substances (pharmaceuticals, homeopathic compounds, etc) and that it is desirable for a composition used in medical, pharmaceutical, and/or homeopathic applications to remain sterile. The combined limitations of claims 1-11 of the instant application are obvious over the limitations of claim 29 of copending '010, including an active substance (e.g. decongestant, such as oxymetazoline hydrochloride), glycerin, carrageenan, sugar, guar gum, methylcellulose, carbohydrate thickeners, aloe, permeation enhancers, preservatives, and sequestering agents.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 2, 3, 5, 21, 22, 28, and 30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, and 5 of copending Application No. 11/163,876 (copending '876). Although the conflicting claims are not identical, they are not patentably distinct from each other because these claims are overlapping in scope.

Claims 1, 2, 3, 5, 21, 22, 28, and 30 of the instant application are obvious over claims 1, 4, and 5 of copending '876, because copending '876 teaches a medicant delivery system comprising a delivery device with a delivery portion and a handle portion. The handle portion is obvious over the elongated stick component of the applicator assembly and a delivery portion is obvious over an applicator. Furthermore, '876 teaches a medicant having a viscosity between about 6,000 to about 20,000 centipoise which meets the limitation of claim 1, requiring a composition viscosity greater than 1,500 centipoise.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-7, 21, 22, 24, 25, 28-30, and 35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 23-27, 29, 31, 32, and 34 of copending Application No. 11/028,991 (copending '991) in view of Seifert (U.S. P.N. 5,100,028; USPN '028). Although the conflicting claims are not identical, they are not patentably distinct from each other because these claims are overlapping in scope.

Seifert teaches a **rupturable flexible fluid dispenser** includes a flexible fluid-containing vessel, which has a seal, which **seals a top wall of the vessel to a bottom wall** and is shaped to concentrate in a region thereof forces resulting from pressure generated **by applying a force to the dispenser.** The dispenser contains an applicator similar in design and shape to that claimed in the instant application (title, abstract, Figures 1-3).

Seifert teaches that the applicator may be used to apply a **sterile dosage of cream to the body or to apply a chemical to a particular surface** (column 5, lines 2-4). The word chemical is understood to encompass the term active substance.

The combined limitations of claim 23-27, 29, 31, 32, and 34 of USPN '028 are obvious over the limitations of claims 1-7, 21, 22, 24, 25, 28-30, and 35 of the instant application, in view of Seifert.

It would have been obvious to a person of ordinary skill at the time of the instant application to combine the teachings of Seifert and copending '991, because Seifert teaches that his applicator may be used to apply a sterile dosage of cream to any part of the body and chemicals to a surface. It would have been apparent to a skilled artisan that the term "chemical" encompasses active substances (pharmaceuticals, homeopathic compounds, etc) and that it is desirable for a composition used in medical, pharmaceutical, and/or homeopathic applications to remain sterile.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Claim 27 is objected. Claims 1-35 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni (Paddy) Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James H. Alstrum-Acevedo, Ph.D.
Examiner

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER